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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/679,147	10/05/2000	Tomoki Todo	066683/0188B	7711

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT PAPER NUMBER

1632

DATE MAILED: 03/19/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Advisory Action

Application No.  
**09/679,147**

Applicant(s)

Todo

Examiner  
**Anne Marie Wehbé**

Art Unit  
**1632**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Nov 18, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on Dec 16, 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE:

3. ☒ Applicant's reply has overcome the following rejection(s):  
The rejection of claims under 112, second paragraph, and the rejections under 102 over Barber or Hollenbaugh.

4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
see attached sheets.

6. ☒ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 1-56

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

10. ☐ Other: \_\_\_\_\_

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**Attachment to Advisory Action**

Claims 1-56 stand rejected under 35 U.S.C. 112, first paragraph. Applicant's claims amendments and arguments have not overcome the following issues for reasons of record: 1) lack of enablement for making and using soluble co-stimulatory molecules other than B7-1-Ig or B7-2-Ig; 2) lack of enablement for the use of vectors other than HSV vectors; and 3) lack of enablement for vectors capable of "targeting" particular types of cells. In regards to issue 1), the previous office action stated the evidence provided, i.e. the specification and publications by Kato et al., Kanner et al., Noelle et al., and Hurtado et al., do demonstrate that it was within the skill of the artisan to make a soluble co-stimulatory molecule comprising the extracellular domain of a co-stimulatory molecule and IgG. However, the evidence does not provide enablement for making soluble co-stimulatory molecules that do not contain IgG. In regards to 2), the two vectors discussed by the applicants in their response are both HSV vectors. The previous office actions have addressed in detail the unpredictability of using any and all vectors in applicant's instant invention, and the fact that the specification also does not provide an enabling disclosure for using any vector/promoter combination to express therapeutic amounts of B7-1-Ig *in vivo*, citing Verma et al., Marshall et al., Orkin et al, and Fry et al. and Roth et al. In regards to 3), claim 2 continues to recite wherein the vector is "targeted" to tumor cells. The previous office actions provided substantial evidence regarding the lack of predictability in targeting vector delivery and gene expression to particular cell types *in vivo*, citing Deonarian and Miller.

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Claims 23, 32, and 54-56 stand rejected under 35 U.S.C. 102(a) over Sturmhoefel et al. The applicant has amended the claims to recite a soluble costimulatory factor in the B7 family, and specifically B7-1-Ig. Sturmhoefel et al. teaches the construction of a plasmid vector encoding a soluble B7-1-Ig or B7-2-Ig fusion protein capable of transfecting mammalian cells (Sturmhoefel et al., pages 4964-4965). Thus, applicant's amendment does not overcome this art.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER

